

REMARKS

Entry of this Preliminary Amendment before continued examination of the instant application is respectfully requested. Upon entry of this Preliminary Amendment, claims 1, 7-10, 18, 20, and 21 remain in the application. Claims 11-14, 16, and 17 were withdrawn. Reconsideration of the claims is respectfully requested.

Claims 1, 7, 18, 20, and 21 stood rejected (in the Final Office Action of August 3, 2009) under 35 U.S.C. § 103(a) as being unpatentable over Groll (U.S. Patent Publication No. 2005/0019953) in view of Burke, et al. (U.S. Patent Publication No. 2008/0098802) and Ward (U.S. Patent No. 5,410,504). The Examiner asserted that the combination of Groll, Burke, and Ward renders obvious independent claims 1, 18, and 21.

Applicants respectfully disagree with the Examiner's instant rejection for the reasoning provided below.

Independent claims 1 and 21 are both directed to a self-calibrating disposable blood **test device**, while independent claim 18 is directed to a self-calibrating, disposable **test strip**. At the outset, Applicants point out that a test strip is an example of a test device (see, e.g., page 5, lines 1-2 of Applicants' application as filed). Applicants' application further recites that the test device/strip 14 may be inserted into a meter 12 (see page 5, lines 1-2 and Fig. 1). Thus, Applicants' test device/strip is clearly *different* from the meter. Claims 1, 18, and 21 (as well as withdrawn claim 11) have been amended to further clarify this fact, and such claims now recite, in some form, "[a] self-calibrating, disposable blood test device *insertable in a meter...*" (Emphasis added.)

Applicants' claims 1, 18, and 21 further recite, in some form, that the *test device/strip includes* an information storage portion configured to store information indicative of at least one calibration value of the chemical reagent for calibrating operation of the meter to accurately measure and monitor a test of the blood analyte.

Groll discloses that a ROM key having calibration data encoded thereon. The ROM key may be inserted into a test meter, and the calibration data may then be loaded into the meter. When the test strip is inserted into the test meter, the meter compares, e.g., the calibration data loaded into the meter with that of the test strip. If, for example, a match

does not exist, a signal may be generated that warns the user of the meter, giving the user a chance to insert a correct test strip or to insert a different ROM key into the meter. (See paragraphs [0066] and [0067] of Groll.) In other words, the *ROM key or the test meter* in Groll includes the calibration information; not the test strip itself. Such is in sharp contrast to Applicants' claims 1, 18, and 21, which recite, in some form, that the calibration information is stored in an information storage portion of the test strip.

Applicants further submit that Burke and Ward *fail* to supply the deficiency of Groll identified above.

For all the reasons stated above, it is submitted that Applicants' invention as defined in independent claims 1, 18, and 21, and those claims depending ultimately therefrom, is not anticipated, taught or rendered obvious by Groll, Burke, and Ward, either alone or in combination, and patentably defines over the art of record.

Claims 8-10 stood rejected (in the Final Office Action of August 3, 2009) under 35 U.S.C. § 103(a) as being unpatentable over Groll, Burke, and Ward, and further in view of Mandecki (U.S. Patent Publication No. 2002/0006673). For the reasoning provided above, it is submitted that the combination of Groll, Burke, and Ward fails to disclose all of the elements of independent claim 1, from which claims 8-10 ultimately depend. It is further submitted that Mandecki fails to supply the deficiencies of Groll, Burke, and Ward. Since the combination of Groll, Burke, Ward, and Mandecki does not disclose all of the elements of independent claim 1, Applicants submit that claims 8-10 are patentable at least because of their dependency from claim 1. As such, it is submitted that Applicants' invention as defined in independent claims 8-10 is not anticipated, taught or rendered obvious by Groll, Burke, Ward, and Mandecki, either alone or in combination, and patentably defines over the art of record.

It is submitted that the absence of a reply to a specific rejection, issue or comment in the instant Final Office Action does not signify agreement with or concession of that rejection, issue or comment. Finally, nothing in this Preliminary Amendment should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this Preliminary Amendment, and the amendment

of any claim does not signify concession of unpatentability of the claim prior to its amendment.

In summary, claims 1, 7-10, 18, 20, and 21 remain in the application, and claims 11-14, 16, and 17 are withdrawn. It is submitted that, through this Preliminary Amendment, Applicants' invention as set forth in these claims is in a condition suitable for allowance.

Further and favorable consideration is requested. If the Examiner believes it would expedite prosecution of the above-identified application, she is cordially invited to contact Applicants' Attorney at the below-listed telephone number.

Respectfully submitted,

DIERKER & ASSOCIATES, P.C.

/Julia Church Dierker/

Julia Church Dierker
Attorney for Applicants
Registration No. 33368
(248) 649-9900, ext. 25
juliad@troypatent.com

3331 West Big Beaver Rd., Suite 109
Troy, Michigan 48064-2813
Dated: December 2, 2009
JCD/AMS